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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,302

12/09/2003

William F. Weitzel

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT

PAPER NUMBER

3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/731,302

Applicant(s)

WEITZEL ET AL

Examiner

Jaworski Francis J.

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3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-16 and 34-40 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 22-28, 31-33, 41-43, 46-48 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 20, 21, 29, 30, 44 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 4, 7 – 9, 17 – 19, 22 – 28, 31 – 33, 41 – 43, 46 - 48 as amended are rejected under 35 U.S.C. 103(a) as being obvious over de Korte et al (Phys. Med. Biol. 45(2000) pp.1465 – 1475, of record), further in view of Cespedes et al (US6165128).

De Korte as earlier noted proposed both in vivo and in vitro elastographic strain imaging of the layers within the arterial wall, where in the in vitro case an altering force is applied by the researcher (In the in-vivo case measurements are taken at two near-

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diastolic pressure points in the cardiac cycle without an altering force applied and therefore there is no anticipatory reading however see below).

In the former in vitro case which is detailed in Section 3 and Figure 1 of that article, there is described a method of measuring local arterial strain for an arterial wall which deforms in response to the transmural force of physiologic pressure, comprising

altering the transmural force from 80 to 100 mmHg,

measuring changes in position at locations within the arterial wall from these altered forces in the physiologic pressure range by using cross-correlation function peaks, and

determining a strain value and expressing it as an imaged color based on the measured amount of local position change. Whereas in deKorte et al the particular specimen was examined in vitro for purposes of transmural force alteration, it would have been obvious in view of Cespedas et al col. 3 top, col. 5 lines 36-37 and col. 7 lines 47 – 59 that since the human iliac artery was examined in vitro, the use of an applied endoluminal pressure increment for in vivo elastography within conduits and vessels was known and Cespedas et al were recommending an in vivo clinical implementation such as for clinical iliac artery elastography such that the implementation of same would have been an expected progression. Additionally as noted earlier in the in vivo case practiced on coronary arteries of patients, deKorte et al for its part described that two near-diastolic points in the heart's pressure wave are the measurement points at greater and reduced transmural pressure. While de Korte et al elected to not use the IVUS catheter balloon to apply force in vivo (a conclusion drawn

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from page 1469, bottom and page 1473 para next-to-last, since de Korte et al elsewhere in Section 2.3, end-sentence state that IVUS balloon pressure application is a known equivalent to native physiologic pressure use it would then have been obvious to use the applied balloon pressure albeit this is a less-favored approach in a cardiac patient exhibiting symptoms in that particular study.

(Claim 1)

The strain value is intrinsically non-linear in relation to the hardness variation of atheromatous components.(claim 2).

The imaging is non-invasive because the artery specimen isn't inside a biological organism anymore. (claim 3).

Since two applied pressure values are used, the lesser or 80mm Hg may be regarded as a reduction with respect to the greater 100mm Hg value. (Claims 4,7).

Since claim 8 merely restates the intrinsic nature of arterial walls, it is grouped here.

Rejection of claims 17-19 and 22 - 28 parallels the arguments supra, and with regards to the system for carrying out the method.

Allowable Subject Matter

Claims 5 – 6, 20 – 21, 29 – 30, 44 - 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 10 – 16, 34 - 40 are allowed.

Response to Arguments

de Korte et al considered together with Cespedes et al extends the transmural applied force concept to measurement of local properties within the wall e.g. by production of an elastographic image thereof as an analogy to heretofore conventional pressure application within other body conduits to obtain the elastographic measurement and suggests that this may extend to in vivo arterial measurements.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

US5265612 as acknowledged in the former is cited to complete the case record..

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

01252007


Francis J. Jaworski
Primary Examiner